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APPLICATION NUMBER	FILING DATE		FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.		
	69/24/93	ATELINSOM		J	W010101P	
				Total and	EXAMINER	\neg

PATREA L. PASST ARNALL GOLDEN & GREGORY 2800 ONE ATLANTIC CENTER 120: WEST PEACHIREE STREET ATLANTA, GA 30309

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ARTUNIT PAPER NUMBER

1812

DATE MAILED:

09/16/96

This is a communication from the examiner in charge of your application.

COMMISSIONER OF FATERITS AND TRADEMARKS	
OFFICE ACTION SUMMARY	
X Responsive to communication(s) filed on <u>もねら</u>	
X This action is FINAL.	
Since this application is in condition for allowance except for formal matters, prosecution accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213.	n as to the merits is closed in
A shortened statutory period for response to this action is set to expire 3 whichever is longer, from the mailing date of this communication. Failure to respond within the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtain 1.136(a).	the period for response will cause
Disposition of Claims	
Claim(s) 1,3-5, 8-16, 18-20, 23-32, 34	is/are pending in the applicati-
Of the above, claim(s) 1, 3-5, 10-16, 18-20, 25-32, 34	is/are withdrawn from consideration
Claim(s)	
\Box Claim(s) $8-9$, $23-24$	
☐ Claim(s)	
☐ Claims are subj	ect to restriction or election requirem
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.	
☐ The drawing(s) filed on is/are objected	to by the Examiner.
☐ The proposed drawing correction, filed on	•
☐ The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).	
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have	been
☐ received.	
☐ received in Application No. (Series Code/Serial Number)	
received in this national stage application from the International Bureau (PCT Rule	17.2(a)).
*Certified copies not received:	
Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachment(s)	
Notice of Reference Cited, PTO-892	
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).	
Interview Summary, PTO-413	
□ Notice of Draftsperson's Patent Drawing Review, PTO-948	
□ Notice of Informal Patent Application, PTO-152	
- SEE OFFICE ACTION ON THE FOLLOWING PAGE	:e _

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DETAILED ACTION

Information Disclosure Statement

1. Applicant is reminded that the form 1449 filed with the IDS of 1/22/96 is incomplete in several citations. Please see Paragraph No. 4, Paper No. 18.

Double Patenting

2. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 5,545,619. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap; e.g. the instant claims recite changes at positions 109-112 (NAAH), 114-117... 121 (STKP...Q); 116 (K); and 116-117 (KP) which are identical to particular species recited in '619.

Applicant's amendment of claim 9 removed certain of the species which overlap; however, certain other overlapping species remain. Therefore, this rejection is maintained for reasons of record.

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Claim Rejections - 35 USC § 112

4. Claims 8-9 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the "analog of a protein" in claims 8 and 9 refers to since the analog is not clearly defined in the preamble of the claims. In addition, it is not clear whether "those complement regulating proteins wherein the carboxy terminus is removed" refers to those proteins which are recited in the claims or if it refers to other complement regulating proteins. It is suggested that the preamble of claims 8 and 9 be amended such that it is comparable to that of claim 1 of U.S. Pat. No. 5,545,619, such that it recites:

An analog of a protein [regulating complement activation having short consensus repeats of amino acid sequence] selected from the group consisting of complement receptor 1, complement receptor 2, decay accelerating factor, membrane cofactor protein, C4 binding protein, and factor H, and [those] these complement regulating proteins wherein the carboxy terminus is removed to allow the protein to be secreted, wherein the protein analog contains [a change within a] amino acid substitutions in the short consensus repeats [that] which correspond [with a change to] to amino acid substitutions in the short consensus repeats of complement receptor one [as shown in] (SEQ ID NO: 13) selected from the group consisting of:

Claims 23-24 are unclear because "the protein analog" lacks antecedent basis in the claim, and thus it is unclear whether the claimed method is directed to making the protein analog or another type of protein. It is suggested that the claims be amended to recite:

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A method for making a protein <u>analog</u> [regulating complement activation having short consensus repeats of amino acid sequence] selected from the group consisting of complement receptor 1, complement receptor 2, decay accelerating factor, membrane cofactor protein, C4 binding protein, and factor H, and [those] <u>these</u> complement regulating proteins wherein the carboxy terminus is removed to allow the protein to be secreted, wherein <u>the amino acid sequence</u> of the protein analog is changed <u>by amino acid substitutions in the</u> [a] short consensus repeats [to] which correspond to <u>amino acid substitutions in the short consensus repeats of complement</u> receptor one [as shown in] (SEQ ID NO: 13) selected from the group consisting of:

Conclusion

- 5. The claims are free of the prior art of record.
- 6. Applicant's arguments that the remaining claims in the instant application should be examined are not persuasive because as discussed previously, in Paragraph No. 3, Paper No. 18, none of the pending, non-examined claims are generic to the examined species. However, claims drawn to the species elected in Paper No. 8, which includes complement regulatory proteins in which various SCRs are swapped between different proteins as well as truncated variants thereof, would be examined if claims presented to only those species were presented. Please see Paper No. 8 for the claims that were examined in that Office Action.
- 7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Karen E. Brown at (703) 308-3667, fax number (703) 308-0294. The Examiner can normally be reached Mondays through Fridays from 8:30 a.m. to 5:00 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Stephen Walsh, can be reached at (703) 308-2957.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist at (703) 308-0196.

(U) Karen E. Brown 13 September 1996

> STEPHEN G. WALSH PRIMARY EXAMINER GROUP 1800